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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

JENNIFER CROUCH, individually and )	
on behalf of all others similarly situated, )	No. 2:09-cv-02905-DMC-MF
)	
Plaintiff, )	
)	
v. )	RETURN DATE: June 7, 2010
)	
JOHNSON & JOHNSON CONSUMER )	
COMPANIES, INC; KIMBERLY )	
CLARK CORPORATION; WAL- )	
MART STORES, INC.; and JOHN DOE,) )	
)	
Defendants. )	
)	

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**PLAINTIFF'S OPPOSITION TO DEFENDANTS JOHNSON &  
JOHNSON CONSUMER COMPANIES, INC., AND WAL-MART STORES,  
INC.'S MOTIONS FOR RECONSIDERATION**

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## I. INTRODUCTION

Defendants' Motions for Reconsideration<sup>1</sup> should be denied. Nowhere in their Motions do Defendants deny that methylene chloride, a probable carcinogen and one of only 11 chemicals banned by the Food & Drug Administration ("FDA") as an ingredient in cosmetic products, has been found in their baby shampoos and washes. Instead, they argue that because they did not "identify" methylene chloride on their label, it is not an "ingredient" in their shampoo or wash, and thus they are free to allow a hazardous chemical and probable carcinogen to contaminate their products. Such an argument is absurd and does not form a basis for reconsideration of Plaintiff Crouch's consumer claims under state law. Defendants offer no sufficient factual basis for this Court to determine that methylene chloride was *not* an ingredient. Rather than presenting a clear issue of law, Defendants' new theory at best creates a novel factual dispute that requires discovery and expert testimony prior to any ruling. This Court did not err in its Opinion (Dkt. No. 50) ("MTD Op."), and Defendants' attempt to have a second bite at the apple through these Motions for Reconsideration should be denied.

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<sup>1</sup> See Brief in Support of Defendant Johnson & Johnson Consumer Companies, Inc.'s Motion for Reconsideration Pursuant to Local Civil Rule 7.1 (Dkt. No. 55-1) ("J&J Mot."); Brief in Support of Defendant Wal-Mart Stores, Inc. In Support of Motion for Reconsideration Pursuant to L. Civ. R. 7.1 (Dkt. No. 54-1) ("Wal-Mart Mot.").

## II. ARGUMENT

### A. Defendants Have Not Met Their Burden for Reconsideration of the Court's Prior Orders.

#### 1. A Motion for Reconsideration Is an “Extraordinary Remedy” and Improper Here.

A motion for reconsideration is an “extraordinary remedy” that is granted “very sparingly.” *See NL Indus. Inc. v. Commercial Union Ins. Co.*, 935 F. Supp. 513, 516 (D.N.J. 1996). As Judge Orlofsky in the District of New Jersey observed:

Not only are [motions for reconsideration] not a substitute for the appellate process, such motions are *not* an opportunity to argue what could have been, but was not, argued in the original set of moving and responsive papers. Similarly, such motions are not an opportunity for the parties to avail themselves of additional briefing, that is, to circumvent the Local Civil Rules governing the size and length of briefs.

*Bowers v. Nat’l Collegiate Athletic Ass’n*, 130 F. Supp. 2d 610, 613 (D.N.J. 2001)

(emphasis in original). These limits, which are based upon the law of the case doctrine, protect “both [the] court and parties against the burdens of repeated reargument by indefatigable diehards.” Wright, Miller, and Cooper, 18B Fed. Prac. & Proc. Juris. § 4478 (2d ed.).

Defendant Johnson & Johnson Consumer Companies, Inc. (“J&J”) attempts to circumvent these standards by arguing that its new “ingredient” argument is proper because (1) “challenges to subject matter jurisdiction may be raised and considered by the Court at any time”; and (2) J&J was “under no obligation to affirmatively refute

points not even alleged.” J&J Mot. at 4.<sup>2</sup> J&J is wrong on both points. While jurisdiction “may generally be raised for *the first time* at any stage of the litigation,” *Gutin v. Washington Township Bd. of Educ.*, No. 04-1947, 2007 WL 2139376, \*2 (D.N.J. July 23, 2007) (emphasis added; quoting *Sedivy v. Richardson*, 485 F.2d 1115, 1116-17 (3d Cir. 1973)), here, of course, Defendants’ Motions represent the sixth time they have raised standing issues in this matter. *See Gutin*, 2007 WL 2139376 at \*1 n.1 and \*3 n.9 (holding that the motion was improperly styled as a “motion for reconsideration” since, due to the unique posture of the case, the standing issue arose for the first time at summary judgment and had not previously been briefed). As shown, Defendants have had ample opportunity to brief their standing issues in their motions to dismiss; they have always been on notice of the FDA regulations banning methylene chloride as an ingredient in cosmetics; and if they wanted to challenge Plaintiff’s standing because methylene chloride is not an “ingredient,” then they could and should have done so in their prior briefing.

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<sup>2</sup> Defendant J&J purports to incorporate arguments from Wal-Mart’s brief regarding the Kentucky Products Liability Act, but Plaintiffs cannot locate these phantom arguments *anywhere* therein. *See* J&J Mot. at 1 n.1. Defendant J&J’s Motion is also an improper reply to Plaintiffs’ previous oppositions to Defendant J&J’s motions for reconsideration in *Vercellono*, No. 09-02350 (Dkt. No. 83), and *Levinson*, No. 09-03317 (Dkt. No. 48). *See* J&J Mot. at 4; L. Civ. R. 7.1(d)(3) (“No reply papers shall be filed on a motion for reconsideration . . .”). These phantom arguments and improper tactics do not constitute grounds for reconsideration of the Court’s Opinion in this case, or in *Vercellono*, No. 09-02350 (Dkt. No. 74) and *Levinson*, No. 09-03317 (Dkt. No. 39).

Given the multiple motions to dismiss and seriatim motions for reconsideration from Defendants, this case stands in stark contrast to situations where “extraordinary circumstances” justify revisiting the standing question. *See Public Interest Research Group of New Jersey v. Magnesium Elektron, Inc.*, 123 F.3d 111, 118 (3d Cir. 1997) (“*PIRG*”) (“courts may reconsider issues that impinge on their jurisdictional powers, as enumerated by Article III of the Constitution, when *extraordinary circumstances* warrant such reconsideration” (emphasis added)). No extraordinary circumstances exist here. Defendants present no intervening change in the controlling law, nor can they claim the “evidence” they rely on — *i.e.*, federal and state regulations, industry publications, and FDA inspection guidelines — was not previously available. That leaves only the “necessary to correct a clear error of law or prevent manifest injustice” prong, and Defendants’ theory — that the presence of banned, yet hidden, toxins in their baby shampoo should not form the basis for standing — is no basis on which to determine that this Court’s earlier ruling was “a clear error of law.” Indeed, this Court’s Opinion is completely consistent with the FDA regulations governing methylene chloride and its prior opinions issued in *Vercellono*, No. 09-02350 (Dkt. No. 74) and *Levinson*, No. 09-3317 (Dkt. No. 39).

This Court has not “overlooked” anything, and there is no ground for reconsideration of this Court’s conclusion that Plaintiff Crouch has standing to pursue



her claims. *See* L. Civ. R. 7.1(i) . Because Defendants have not met their burden, Plaintiff Crouch respectfully requests that this Court deny Defendants’ motions.

**B. This Court Has Made No Error of Law or Fact.**

**1. This Court’s Ruling Did Not Hinge on Methylene Chloride’s “Ingredient” Status in Defendants’ Baby Shampoo and Wash.**

This Court has already held Plaintiff Crouch possesses standing to bring claims against J&J and Wal-Mart Stores, Inc. (“Wal-Mart”) for baby products which were contaminated with methylene chloride. The Court’s holding did not, as Defendants assert, turn on whether methylene chloride is an ingredient in Defendants’ products under the FDA’s highly technical regulations. Instead, the Court held, “[I]nsofar as Plaintiffs’ claims pertain to methylene chloride, a chemical explicitly banned for use by the FDA in any cosmetic, this Court declines to dismiss Plaintiffs’ claims pursuant to Fed. R. Civ. P. 12(b)(1) for lack of standing.” MTD Op. at 8. In reaching this conclusion, this Court noted Plaintiff’s allegation “that despite representations made by these companies that their products are safe and gentle, these products *contain contaminants* that are not disclosed on the label and that could otherwise have been removed pursuant to a process called vacuum stripping.” *Id.* at 2 (emphasis added). Thus, this Court found the Plaintiff had standing *based upon the presence of a banned chemical* in Defendants’ baby products, *not* the chemical’s “ingredient” status in Johnson’s Baby Shampoo or Equate Tearless Baby Wash.

**2. Defendants Offer No Basis for Concluding that Methylene Chloride Was *Not* an Ingredient in Their Products.**

Even if, as Defendants allege, this Court's Opinion turned on the "assumption" that methylene chloride was an ingredient in Defendants' products, Defendants have offered *no* rational basis for concluding that methylene chloride was not an ingredient in their baby products.

Their first contention, that methylene chloride is not an "ingredient" under the FDA regulations because it was not listed on their product labels, is specious and absurd. Defendants essentially assert that they can have any banned or toxic chemical in their product that they want, so long as they don't disclose it as an "ingredient" on their label. The consumer protection acts and implied warranty claims raised in Plaintiff Crouch's complaint demand more, and Plaintiff bargained for more. As this Court appropriately recognized, Plaintiff suffered injury when her allegedly "safe" products were contaminated with an undisclosed toxin that Defendants knew or should have known was in the baby products.

Their second contention is that standing should now be denied because methylene chloride is allegedly present in the baby shampoo and wash only in "de minimis" amounts. *See* Wal-Mart Mot. at 4; J&J Mot. at 7. However, Defendants do not deny that the hazardous chemical is in their products, and the FDA regulation does not have a carve-out for "de minimis" ingredients. 21 C.F.R. § 700.19(b). The regulation bans methylene chloride as an ingredient, period. *Id.* Thus, Defendants'

arguments are not legal arguments about standing, but factual attacks under Federal Rule of Civil Procedure 12(b)(1), and Plaintiff is entitled to discovery on such issues. *See* J&J Mot. at 7-9, Wal-Mart Mot. at 4-6; *see also* discussion at section B.3, *infra*. Indeed, the Court already acknowledged that there may be a factual dispute as to whether the chemicals contained in the products are dangerous in amount when it held that Plaintiff had standing and her claims could proceed to discovery. MTD Op. at 7-8.<sup>3</sup>

### **3. Defendants May Not Introduce New Factual Matters on a Motion for Reconsideration.**

On a motion for reconsideration, a court may only consider factual matters or controlling decisions which “*were presented to the court* but were overlooked.” *Capogrosso v. State Farm Ins. Co.*, No. 08-2229, 2009 WL 5171865, at \*2 (D.N.J. Dec. 23, 2009) (emphasis added; citation omitted). Defendants’ Motions for Reconsideration introduce new factual matters and non-controlling, irrelevant materials, such as the FDA’s non-binding inspection guidelines, inapplicable

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<sup>3</sup> Similar cases alleging toxins in products intended specifically for children have routinely proceeded to discovery. *See, e.g., In re Mattel, Inc. Toy Lead Paint Prods. Liab. Litig.*, 588 F. Supp. 2d 1111, 1117 (C.D. Cal. 2008) (plaintiffs’ warranty and consumer protection claims regarding defective toys containing magnets or lead paint upheld on motion to dismiss); *In Re Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig.*, No. 08-1967, 2009 WL 3762958 at \*2 (W.D. Mo. Nov. 9, 2009) (holding that plaintiffs’ consumer claims regarding BPA in baby bottles, a substance not banned by the FDA, could proceed to discovery on fraudulent and negligent omissions of material fact (under common law or statute) and breach of implied warranty of merchantability).

regulations regarding coffee and pharmaceuticals, and California state regulations regarding exposures as opposed to concentrations. Defendants' apparent "brief-writer's remorse" should not be indulged. Further, these new factual matters present an improper collateral attack on the Federal Rules of Civil Procedure 8 and 12 pleading standards that are applicable at this stage in the litigation.

**a. Defendants' Factual Attack on Plaintiff's Standing Requires Jurisdictional Discovery.**

Consideration of these new factual materials is procedurally improper on a Federal Rule of Civil Procedure 12(b)(1) motion since Defendants made a facial attack to Plaintiff's standing. The Court must accept the allegations of the complaint as true, and not look beyond the face of the complaint to determine jurisdiction. *See Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176-77 (3d Cir. 2000) (when reviewing a facial attack, the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff); *Mortensen v. First Fed. Sav. and Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977); *Int'l Ass'n of Machinists & Aerospace Workers v. Nw. Airlines, Inc.*, 673 F.2d 700, 711 (3d Cir. 1982) (a Rule 12(b)(1) motion constitutes a facial attack where no affidavits, depositions or other factual matters were presented to the court for consideration). With this motion, Defendants switch from a facial to a factual attack. *See* J&J Mot. at 9-10 n.4; Wal-Mart Mot. at 6 (referring to the FDA's inspection guidelines). At a minimum, this switch entitles Plaintiff to discovery as to facts

bearing on jurisdiction. *See Metallgesellschaft AG v. Foster Wheeler Energy Corp.*, 143 F.R.D. 553, 558-59 (D. Del. 1992) (citing *Mortensen*, 549 F.2d at 890-91); *see also* Moore's Federal Practice § 12.30[3] (3d ed. 2009).

**b. Defendants' New, Irrelevant, and Non-Controlling Materials Do Not Warrant Reconsideration.**

Even if it were proper for the Court to consider this new factual material, which it is not, Defendants do not meet their burden to show that these materials either (1) warrant reconsideration of the Court's prior Opinion; or (2) warrant resolution at the motion to dismiss stage. At best, Defendants raise new issues of fact which should be addressed after discovery.

**(i) The FDA's Guide to Inspections**

First, Defendants rely heavily on the FDA's "Guide to Inspections of Cosmetic Product Manufacturers." *See* J&J Mot. at 8-10; Wal-Mart Mot. at 6. On its face, the FDA Guide declares that it "does not bind [the] FDA" and provides no "immunities."<sup>4</sup> And since the face of the document provides no support for Defendants' position, it is,

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<sup>4</sup> In relevant part, the FDA Guide states that it is "reference material for investigators and other FDA personnel. The document does not bind FDA, and does no [sic] confer any rights, privileges, benefits or immunities for or on any person(s)." U.S. FOOD & DRUG ADMINISTRATION, GUIDE TO INSPECTIONS OF COSMETIC PRODUCT MANUFACTURERS (Feb. 1995), <http://www.fda.gov/ICECI/inspections/inspectionguides/ucm074952.htm> (last visited Feb. 25, 2010). Thus, Defendants are attempting to use this authority for a purpose for which it was *never* intended by the FDA: to shield their companies from potential liability regarding toxins in children's shampoo and similar products.

again, at best a factual issue whether this document provides any justification for the methylene chloride in Defendants' baby products.

The FDA Guide also states that methylene chloride is prohibited as a cosmetic ingredient, but not as an "unintentional contaminant[]" of cosmetics manufactured in accordance with good manufacturing practices." Thus, questions of fact that can only be appropriate for *discovery* — not newly raised on a Motion for Reconsideration — include (1) whether the presence of this contaminant that was banned as an ingredient is *intentional*; and (2) whether Defendants' "cosmetics were manufactured in accordance with good manufacturing practices."

Further, Defendants wrongly contend that "Plaintiff's allegations regarding methylene chloride as a[] 'contaminant' fall short of the plausibility requirement of *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009)." J&J Mot. at 9; Wal-Mart Mot. at 6. Defendants' argument fails because Plaintiff's allegations are specific and plausible. Plaintiff's Amended Complaint (Dkt. No. 16) ("PAC") demonstrated that other products — including products manufactured by J&J — were *not* contaminated with methylene chloride (*see* PAC at ¶¶ 53-71), and that methylene chloride could be removed by vacuum-stripping (*see* PAC at ¶¶ 15-17). Consequently, Plaintiff plausibly alleged that, due to methylene chloride contamination, Defendants' products were not "manufactured in accordance with good manufacturing practices." Even on Defendants' reading, products manufactured in accordance with good manufacturing

practices should not contain methylene chloride, and Plaintiff's allegations easily meet the *Iqbal*, 129 S. Ct. at 1937, requirements.

Plaintiff also alleged that Defendants *knew or should have known* that their products were contaminated with methylene chloride, thus plausibly alleging that Defendants' products were not "unintentionally" contaminated. *See* PAC at ¶¶ 5, 13. *See Iqbal*, 129 S.Ct. at 1949 (plaintiff must only allege enough facts to "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged").

Defendants' argument that the presence of methylene chloride in baby products bears "no reasonable relationship" to the FDA's ban is itself implausible. *See* Wal-Mart Mot. at 7; J&J Mot. at 10-11. Defendants' position relies on references to inhalation studies and concentrations of methylene chloride in hairspray. *See* 21 C.F.R. § 700.19(a). However, the FDA's ban on methylene chloride does not depend upon whether the cosmetic is an aerosol or hairspray, the concentration level of the chemical, or how the user is exposed to the chemical — *i.e.*, through inhalation, ingestion, or dermal contact. *See* 21 C.F.R. § 700.19(b). The regulation bans methylene chloride as an ingredient, whatever form it takes and in any cosmetic whatsoever. *Id.*

**(ii) Defendant J&J's Citation to Non-Controlling State Law Standards and Industry Publications Does Not Warrant Reconsideration**

The other non-controlling and heretofore undisclosed factual material that Defendant J&J cites in footnote four of its brief lacks merit and is irrelevant. *See* J&J Mot. at 9-10 n.4. Defendant J&J should not be permitted to present to the Court newly-introduced, specious, and misleading “authority” or “evidence” that is, in the case of the *Pharmacopeia* materials, not even attached to J&J’s brief. Drawing a comparison between the results of Plaintiff’s testing, as described in the Complaint (PAC ¶¶ 3, 9, and 10), and the “permissible levels” cited in J&J’s footnote, is scientifically invalid. The numbers represent two different types of concentrations, so comparisons are erroneous.

In its references to the substance of these materials, Defendant J&J only raises new factual disputes by making undisclosed assumptions, engaging in improper comparisons, and failing to account for children’s particular vulnerability to the banned ingredient and probable carcinogen that is contained in Defendants’ products. Such diversions do not necessitate reconsideration. *See Capogrosso*, 2009 WL 5171865 at \*2.

First, J&J tries to refute Plaintiff’s allegations regarding the hazards of methylene chloride by comparing levels in Plaintiff’s products to limits which are



evaluated in terms of micrograms per day ( $\mu\text{g/day}$  or  $\text{mcg/day}$ ).<sup>5</sup> By contrast, the amount of methylene chloride present in Defendant's baby shampoo is expressed as parts per million (ppm). J&J is mixing apples and cabbages (they are not even both fruits so the old "apples to oranges" adage can not apply). The measurements for micrograms per day, a unit of *exposure*, and parts per million, a unit of *concentration*, are *not* comparable. To convert between these two measurements, Defendants would need to engage in numerous assumptions and provide this Court — and Plaintiff — with additional evidence. Defendant J&J fails to provide any basis for its assertion that the concentration of methylene chloride in its product is lower in magnitude than the exposure levels which it cites. J&J Mot. at 9-10 n.4.

J&J's references to the concentration levels of methylene chloride in spices, hops extract, and decaffeinated coffee are similarly inapposite. *Id.* (citing 21 C.F.R. § 173.255). None of these products are a baby shampoo or wash, and the limits that Defendant cites fail to take into account both children's particular vulnerability to methylene chloride and the exposure route. Again, the relevance of these vastly

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<sup>5</sup> See J&J Mot. at 9-10 n.4. Even though J&J improperly uses its Motion as a reply to Plaintiffs' arguments in prior Oppositions in the *Levinson* and *Vercellono* matters, see discussion at n.2, *supra*, J&J fails to correct the errors that Plaintiffs noted in those previous briefs. Thus, J&J continues to err in its citation to the inapposite California standards regarding inhalation levels, which Plaintiff believes was intended to be 27 C.C.R. § 25705 (b) and (c) (2009). Further, J&J incorrectly cites the unit of the levels, stating one of them as *milligrams*, when it actually should have been a unit that is 1,000 times less, expressed in *micrograms*. J&J Mot. at 9-10 n.4.

different substances, ingested in different ways by adults rather than children, can only raise factual issues.

References to limits on hops, spices, and decaffeinated coffee are not probative of the issue here: whether Defendants breached implied warranties and violated consumer protection acts when they sold products that were represented as being safe and gentle for children, but were actually contaminated with a banned ingredient and probable carcinogen.

Defendants have offered no valid basis for reconsidering this Court's conclusion that Plaintiff possesses standing to bring consumer protection claims based upon the presence of a probable carcinogen and skin irritant in a children's product that was marketed as "safe" and "gentle." Defendants' Motions should be denied.

### **III. CONCLUSION**

Defendants have failed to meet their burden of establishing that their motions for reconsideration are appropriate. The Court in its prior Opinion correctly found that Plaintiff had standing to bring her claims for economic injury.

RESPECTFULLY SUBMITTED this 24th day of March, 2010.

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on May 24, 2010, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all parties so registered.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: May 24, 2010

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